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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.			KERR, KATHLEEN M	
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MINNEAPOLIS, MN 55402			1652	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,384

Applicant(s)

SHERMAN ET AL.

Examiner

Kathleen M Kerr

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-55 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 29,30 and 42-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-41 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction (mailed on October 1, 2003), Applicants filed a response and amendment received on November 6, 2003. Said amendment cancelled Claim 1-8 and added Claim 61.

In the previous Office action, the pending claims were incorrectly cited. An amendment filed on March 5, 2002 cancelled Claims 1-28 and 59-60. Thus, Claims 29-58 had been previously pending. By virtue of Applicants' amendment, Claims 29-58 and 61 are now pending.

Election

2. Applicants' election with traverse of Group 45 (Claims 31-41) in the paper filed November 6, 2003 is acknowledged. New Claim 61 falls within the elected Group. The traversal is on the ground(s) that the inventions are closely related. This is not found persuasive because the inventions are only intertwined when a pik gene encoding a protein is linked to the elected pikA promoter on a vector. Otherwise, they are distinct sequences with distinct structures as previously noted. Applicants also seem to argue that all the pending claims can be searched without a serious search burden on the Examiner; however, the distinct sequences of the different genes claimed makes this impossible. Moreover, the search of such large genes is very time-consuming and burdensome on the Office. Applicants also argue the cost of 48 divisional applications is burdensome on the Applicants; this issue is not relevant in consideration of separate and distinct inventions.

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The requirement is still deemed proper and is therefore made FINAL. Claims 29-58 and 61 are pending in the instant application. Claims 29, 30, and 42-55 are withdrawn from consideration as non-elected inventions. Claims 31-41 and 61 will be examined herein.

Priority

3. The instant application requests the revival of PCT/US99/14398 filed June 25, 1999, which application was abandoned after 20 months of filing (no formal demand for examination was filed by Applicants). While the petition is still under consideration (and Applicants should be informed separately of its outcome), said application is not revived herein. Thus, the filing date of the instant application is considered the earliest effective filing date, that is November 19, 2001.

Information Disclosure Statement

4. No information disclosure statement has been filed with the instant application as of the date mailed of the instant Office action. Applicants are reminded that they have a duty to disclose all information, of which they are aware, relevant to the patentability of the pending claims (see 37 C.F.R. § 1.56 and M.P.E.P. § 2000).

Compliance with the Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821

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through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

- a) In Figure 8 and its description on page 13 of the specification, three amino acid sequences are disclosed without benefit of SEQ ID NOs.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

6. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---DNA encoding a Methymycin and Picromycin Promoter---

7. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of all the names of the

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polyketides believed to be produced by the polyketide synthase gene cluster disclosed, i.e., the inclusion of ---narbomycin---, and the inclusion of the source species, *Streptomyces venezuelae* for completeness.

8. The specification is objected to for the following inconsistencies with respect to the Drawings and their Brief Description in the text:

- a) In Figure 7 filed March 5, 2002, both gels are labeled "Fig. 7B"; one is ---A---. Moreover, the description on page 13 must describe Figures 7A and 7B, not just Figure 7.
- b) On page 14, the description of Figure 15 cites 11 enzyme amounts for the depicted curves while only 10 curves are visible. Clarification is required.
- c) On page 15, the description of Figure 23 must describe Figures 23A-23K. Moreover, the text describes one amino acid sequence; however, in Figure 23 (see Figure 23I-23J), two, distinct amino acid sequences are disclosed. Clarification is required.
- d) Figure 31 is mislabeled. When Figures require more than one page, the separate pages must be lettered (not numbered). After ---Z---, double letters, such as ---AA---, should be used and then triple letters if necessary. Moreover, on page 16, in the description of Figure 31, a description of Figure 31A to Figure 31VVV must be found. Additionally, at least four open reading frames are found in Figure 31 (see breaks on 31-32, 31-54, 31-64) yet only one amino acid sequence (SEQ ID NO:6) is disclosed. Clarification is required.
- e) Figure 32 is mislabeled (see above). Moreover, on page 16, in the description of Figure 32, a description of Figure 32A to Figure 32LL must be found. Additionally, at least eight open reading frames are found in Figure 32 (see breaks on 32-6, 32-10, 32-12, 32-19, 32-25, 32-28, and 32-36) yet only one amino acid sequence (SEQ ID NO:4) is disclosed. Clarification is required.
- f) On page 17, Figures 41A-41F must be described, not just Figure 41.

Correction and/or clarification on all of the above points are required.

9. The specification is objected to for having inconsistent references. In some portions of the specification, full citation of a reference is found in the referring passage; in other portions, citation shorthand is found with the full citation being found in an Endnote section on pages 80-

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84. Either one or the other form of reference managing is required for clarity throughout the specification. Additionally, the following are noted in the Endnote section:

- a) On page 82, there are two "Hopwood *et al.*, 1985" references that must be labeled "a" and "b". On page 83, the second Merson-Davies reference is incorrect, a typographical error (duplication) of the first.
- b) On page 83, "Omuras" is a typographical error; the correct reference is ---Omura *et al.*---

Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 39-41 and 61 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 39, the term "leader sequence of pikAI is unclear. Is there a particular portion of SEQ ID NO:5 that is intended (SEQ ID NO:5 is disclosed as containing PikR1, PikR2, PikA1-AIV, pikB, pikC, and pikD)? Clarification of the composition of the intended DNA segment is required.

11. Claim 61 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms like "**a** pikAI gene" and "**a** pikAII gene" (emphasis added) are unclear. The article "a" indicates that more than one pikAI gene can be used; however, the instant specification only discloses a single pikAI gene. Thus, the scope of pikAI genes is unclear. If

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that one, as found in Table 2, is intended, the Examiner suggests using the article ---the--- for clarity. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 31-41 and 61 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to DNA containing a *pikA* promoter; however, none is described in the specification. On pages 32-33, promoters are described and even particularly a *pikA* promoter is mentioned, but none are defined within the framework of the disclosed structure (i.e., SEQ ID NO:5).

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed

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genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, on pages 32-33, promoters are described and even particularly a *pikA* promoter is mentioned, but none are defined within the framework of the disclosed structure (i.e., SEQ ID NO:5). The art does not specifically describe such a genus either. While an art-defined *pikA* promoter would be considered any promoter that promotes expression of *pikA* genes, no structure of such a promoter is described in either the specification or the art. While the sequence of a *pikA* promoter is likely to be found in the sequence 5' of the disclosed *pikA* gene cluster, no specific sequence is disclosed. Thus, one of skill in the art would be unable to predict the structure of any members of this genus by virtue of the instant disclosure.

13. Claims 36, 39-41, and 61 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims, particularly Claim 36, are drawn to an expression cassette containing a thioesterase II (TEII) domain. While other names of domains used in the claims are well known in the art and need no further description, this is not the case for a TEII domain. The written description of TEII domains, particularly to the exclusion of TEI domains, is absent in the specification as filed.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a gene encoding a TEII domain is described in Table 2, for example. The genus of all TEII domains is not described except for its use in the claims. The art does not describe such a genus either. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 31-41 and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 00/00620 (Sherman *et al.*). Sherman *et al.* is the PCT application related (as a continuation parent) to the instant application; the instant rejection is set forth because priority to said document is not granted herein (see priority comments above).

15. Claim 31 is rejected under 35 U.S.C. § 102(b) as being anticipated by Xue *et al.* The instant claims are drawn to DNA comprising a *pikA* promoter.

Xue *et al.* teach the 37948 base pair DNA disclosed in the instant application as having the *pikA* cluster. In as much as this DNA comprises a promoter (see written description rejection above), Xue *et al.* teach this same DNA, and thus, must teach this same promoter.


Conclusion

16. Claims 31-41 and 61 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Kathleen M Kerr
Examiner
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January 20, 2004